

Nov 22 02 09:34a Intervet Inc.

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INTERVET PATENT DEPT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:
THIEL et al.

Serial No.: 09/839,796 Group: 1648

Filed: April 9, 2001 Examiner: S. Foley

For: PESTIVIRUS MUTANTS AND VACCINES CONTAINING THE
SAME

DECLARATION UNDER 37 C.F.R. §1.132

Honorable Commissioner of Patents
Washington, D.C. 20231

Sir:

I, Dr. Birgit Makoschey, declare as follows:

I am a group leader virological mammalian vaccines at Akzo Nobel N.V. (Intervet International BV) and have a Ph.D. in veterinary medicine. I am familiar with the contents of U.S. Patent Application No. 09/839,796. I have supervised a study of the safety and efficacy of 5' deletion mutants of BVDV type I strain CP7.

This study was performed to answer two distinct questions. Firstly, does the deletion of specific sequences within the 5'untranslated region of Bovine viral diarrhea virus (BVDV) result in attenuation of the virus in the target species and secondly, do these deletion mutants protect against subsequent

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challenge infection with pathogenic virus.

The deletion mutants were constructed on the basis of cp7-A5, which is an infectious clone of strain cp 7. In the first part of the study, two groups of five calves were infected both by the intranasal and the intramuscular route with deletion mutants namely with strains Δ2-31 or Δ5-57 respectively. The third group of five calves was infected with cp7-A5. The fourth group of five animals was kept as uninfected control.

Five weeks after the first infection, a challenge virus infection was performed with the BVDV type 1 strain New York. All animals of groups 1 - 3 and three animals of group 4 were challenge virus infected. The two remaining animals of group 4 were kept as uninfected challenge control.

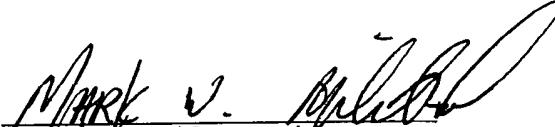
The animals were observed for clinical signs and their body temperature was recorded after first and second infection. Samples were taken to determine white blood cell, lymphocyte and platelet counts as well as to measure viremia and neutralizing antibody titers.

Attorney Docket NO. I/2000.552 US

If the Examiner believes for any reason that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (302) 934-4395, in Millsboro, Delaware.

If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any overpayment to Deposit Account No. 02-2334 for any additional fees required under 37 C.F.R. §1.16 or under 37 C.F.R. §1.17; particularly extension of time fees.

Respectfully submitted,



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Attorney Docket NO. I/2000.552 US

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Enclosure: Version with Marking to Show Changes Made